Application No. : 10/727,155
Filed : December 2, 2003

REMARKS

Claims 1-43 and 46 have been cancelled by way of this amendment. Applicants maintain that the cancellation of a claim makes no admission as to its patentability. Applicants reserve the right to pursue the subject matter of the cancelled claims in this or any other patent application. Claims 44, 45, and 47-51 are withdrawn. New Claims 57-106 have been added. Support for the new claims can be found throughout the specification and claims as originally filed, for example, at paragraphs, [0009], [0010], [0021], [0036], [0043] [0097], [0134]-[0137], [0147]-[0158]. Thus, no new matter has been added by way of this amendment. Claims 44, 45, 47-51, and 57-106 are pending.

In response to the Office Action mailed on December 19, 2005, Applicants submit the following remarks.

Applicants thank the Examiner for extending the search to cover the following species, SEQ ID NOs: 48, 50, 52, 54, 56, and 70.

Notice to Comply with Sequence Rules

A Notice to Comply with Sequence Rules was issued with respect to the amino acid sequences recited in Claims 1-3, 6-8, 10-15, 23-25, 27-29, and 31-36. These claims have been cancelled by way of this amendment. Applicants submit that the application fully complies with the sequence rules.

Rejections under 35 U.S.C. § 112, second paragraph

Claims 16, 17, 37, and 38 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite in the use of the terms "VH3-33," "AK0VK1," "VH3-53," and "L2VK3." Specifically, these terms were alleged to be laboratory designations which do not clearly define the claimed products because laboratories may use the same designations to define completely distinct materials.

Applicants respectfully disagree, and submit that those of ordinary skill in the art would recognize these designations to refer to specific gene families encoding the immunoglobulin variable regions of heavy and light chains. Nevertheless, in the interest of advancing the instant application to allowance, Applicants have cancelled the rejected claims. Thus, the rejection

under this section is now moot. Attention is directed to new Claims 57-106, which no longer claim the antibodies by their specific family genes.

Claims 16, 17, 37, and 38 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite in the recitation of "a human monoclonal antibody" that comprises a "gene."

Applicants have cancelled the rejected claims. Accordingly, this rejection is moot. Attention is drawn to new Claims 57-106, which recite "a fully human monoclonal antibody" that comprises a "polypeptide having the amino acid sequence . . . ."

Rejections under 35 U.S.C. § 112, first paragraph, Enablement

Claims 1-38, 40-43, and 46 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. Specifically, the Examiner argues that the specification, while being enabling for a human monoclonal antibody that specifically binds to Tumor Necrosis Factor-alpha and comprises a heavy chain (SEQ ID NO: 74) containing CDR1 (amino acids 31-35 of SEQ ID NO: 74), CDR2 (amino acids 50-56 of SEQ ID NO: 74) and CDR3 (amino acids 99-114 of SEQ ID NO: 74), and a light chain (SEQ ID NO: 72) containing CDR1 (amino acids 24-34 of SEQ ID NO: 72), CDR2 (amino acids 50-56 of SEQ ID NO: 72) and CDR3 (amino acids 89-97 of SEQ ID NO: 72), and a composition for said antibody, does not reasonably provide enablement for a human monoclonal antibody that specifically binds to Tumor Necrosis Factor-alpha which comprises fewer than 6 CDRs (Claims 1-38), a human monoclonal antibody that binds to Tumor Necrosis Factor-alpha and comprises a VH3-33 (Claim 16) or a VH3-53 (Claim 37) heavy chain gene or an A30VK1 (Claim 17) or an L2VK3 (Claim 38) light chain gene, or conservative variants thereof, a human monoclonal antibody that binds Tumor Necrosis Factor-alpha and comprises heavy and light chain CDRs corresponding to specific canonical classes (Claims 18-22 and 40-43), or a composition comprising a human monoclonal antibody, or functional fragment thereof, that specifically binds to Tumor Necrosis Factor which comprises fewer than 6 CDRs (Claim 46). The Examiner also rejected the terms "conservative variant thereof" in Claims 16 and 37, "comprising" a specific family gene in Claims 16, 17, 37 and 38, "canonical class" in Claims 18-22 and 40-43, and "functional fragment thereof" in Claim 46.

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Applicants strongly disagree with the rejections of these claims and submit that Claims 1-38, 40-43, and 46 are fully enabled by the instant specification. Nevertheless, in the interest of advancing the instant application to allowance, Applicants have cancelled these claims. Accordingly, the rejections under this section are moot. Attention is drawn to new Claims 57-106, which no longer claim the antibodies by their CDRs, family genes, or canonical classes.

Rejections under 35 U.S.C. § 112, first paragraph, Written Description

Claims 1-38, 40-43, and 46 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. Specifically, the Examiner asserts that Applicants were not in possession of a human monoclonal antibody that specifically binds to Tumor Necrosis Factor-alpha and comprises fewer than 6 CDRs (Claims 1-38 and 40-43), a human monoclonal antibody that binds to Tumor Necrosis Factor-alpha and comprises a VH3-33 (Claim 16) or a VH3-53 (Claim 37) heavy chain gene or an A30VK1 (Claim 17) or an L2VK3 (Claim 38) light chain gene, or conservative variants thereof, a human monoclonal antibody that binds Tumor Necrosis Factor-alpha and comprises heavy and light chain CDRs corresponding to specific canonical classes (Claims 18-22 and 40-43), or a composition comprising a human monoclonal antibody, or functional fragment thereof, that specifically binds to Tumor Necrosis Factor-alpha which comprises fewer than 6 CDRs (Claim 46). The Examiner also rejected the terms "conservative variant thereof," "a canonical class," and "functional fragment thereof" in Claims 16, 18-22, 37, 40-43, and 46, and "comprises" a specific family gene in Claims 16, 17, 37 and 38.

Applicants strongly disagree with the rejections of these claims and submit that the subject matter of these claims is described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Nevertheless, in the interest of advancing the instant application to allowance, Applicants have cancelled these claims. Accordingly, the rejections under this section are moot. Attention is drawn to new Claims 57-106, which no longer claim the antibodies by their CDRs, family genes, or canonical classes.

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CONCLUSION

For the foregoing reasons, it is respectfully submitted that the rejections set forth in the outstanding Office Action have been addressed and that the new Claims 57-106 are in condition for allowance. Accordingly, Applicants request the expeditious allowance of the pending claims.

The undersigned has made a good faith effort to respond to all of the rejections in the case and to place the new claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is respectfully requested to call the undersigned to discuss such issues.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: March 20, 2006

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